

National Institute on Deafness and Other Communication Disorders
APPLICATION GUIDELINES FOR RESEARCH CORE CENTERS (P30)

Updates are highlighted in yellow.

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Table Of Contents	Page
I. Introduction	2
II. Requisite Research Base	3
III. Research Cores	3
IV. Administration	4
V. Human Subjects/Vertebrate Animals And Inclusion Of Women, Minorities And Children In Study Populations	5
VI. Preapplication Process	7
VII. Application Format And Content	9
VIII. Review Procedure And Criteria	17
IX. Reporting Requirements And Annual Evaluation	19
X. Sample Documents	20

I. Introduction

This document provides administrative guidelines for Research Core Centers (P30). Applications for Core Centers are sought through a Program Announcement with three receipt dates per year (<http://grants.nih.gov/grants/guide/notice-files/NOT-DC-01-007.html>).

The mission of the National Institute on Deafness and Other Communication Disorders (NIDCD) is to support research and research training on normal processes, as well as diseases and disorders of hearing, balance, smell, taste, voice, speech and language. To achieve this mission, NIDCD employs a number of grant support mechanisms. Among these are various types of research grants, including traditional research project grants, multi-project center grants, career development grants, and individual and institutional National Research Service Awards (training grants).

The Research Core Center Grant (P30) is an institutional award, made in the name of a principal investigator. The Core Center grant is intended to support one or more research cores providing centralized resources and facilities shared by investigators with existing research projects. The aim is to **enhance the research in progress** and to stimulate multidisciplinary approaches to joint research efforts. It should serve as an “intellectual hub” to stimulate and support cooperative and interactive research, to **increase the effectiveness/productivity of current research endeavors and/or to promote new research directions**. Research cores should be designed to furnish a group of investigators some service, technique, or assay to enhance research in progress. Although no funds are provided for direct support of research projects, a Core Center Grant helps to integrate and promote research in existing projects.

Any institution or consortium of institutions with an active program of basic and/or clinical biomedical or behavioral research in one or more of the mission areas of the NIDCD may qualify for support through a Core Center. It is awarded competitively for up to 5 years. The Core Center application should include a description of the requisite research base and research cores. **The application should provide descriptive information on how the cores will provide services to the individual R01s beyond what is currently being provided and/or how the cores will encourage and facilitate collaborative or interdisciplinary work. The application should also describe how each core will be administratively managed and how access and utilization of services will be prioritized.** The P30 does NOT allow for the acquisition of expensive items of equipment or for the conduct of research pilot and feasibility studies.

This document provides information on eligibility and application processes for NIDCD Core Center Grants (P30).

II. Requisite Research Base

A strong research base, as evidenced by a critical mass of funded grants, is a fundamental requirement for, and a major factor in, establishment of a Core Center. At the time of application submission, any institution or consortium applying for the NIDCD Core Center grant must have an active, established program in basic, clinical, and/or epidemiological biomedical or behavioral research in one or more mission areas of the NIDCD.

Institutions applying for a Core Center grant must hold, on the date of grant application submission, a minimum of four NIH research project grants, each with at least one year of support remaining. Research projects associated with a Core Center include individual research grants (R01), FIRST awards (R29), or similar peer-reviewed project funding from other Federal agencies. A current program project/center grant (P01 or P50) subproject may count toward the minimum of four if that subproject will be an “extensive” user of one of the proposed research cores. At least 75% of the research project base must be supported by the NIDCD and focus on NIDCD mission areas. The inclusion of program project and center grant subprojects as part of the allowable research base will diminish over the next several years as the NIDCD transitions to the P30 mechanism and the new clinical research project awards (P50). Training grants (e.g., T32/F32), career development awards (e.g., K08/K23), small grants (R03), AREA grants (R15) and developmental/exploratory awards (R21) do not count as part of the requisite research base, but can be listed as users of the Core Center (see section VII.B.2.).

A Core Center must be an identifiable organizational unit either within a single grantee institution or representing a consortium of cooperating institutions (e.g., geographic or web-based). Joint applications may be submitted by investigators at neighboring, independent, or multi-campus institutions. Duplication of research cores on two different applications from the same institution will receive close scrutiny and must be well justified. Further, individual R01s, R29s, or P01/P50 subprojects cannot be counted as part of the requisite research base on more than one NIDCD P30 application. Competitive supplemental applications requesting an additional research core to existing P30s are allowed, but may not exceed the term of award of the parent P30.

III. Research Cores

The P30 grant supports research cores, shared resources that enhance productivity or in other ways benefit a group of investigators working in areas related to the stated goals of the Core Center. A research core provides a service or resource that enables Core Center investigators to conduct their independently funded individual research projects more efficiently or more effectively, and may through interaction with others lead to new research paradigms and projects. Research cores should be designed to furnish a group of investigators some service, technique, or assay in a manner that will enhance the

research in progress, consolidate resources, and/or contribute to cost effectiveness by providing a service at less cost or of higher quality than if each investigator were to attempt the same process(s) individually. The purpose of each research core may vary in how it serves its users. Cores may also vary in the provision of standard versus innovative services. A research core may also attract new investigators to an area of research by offering specialized services not easily duplicated in an individual laboratory.

One or more research core(s) may be proposed. Each research core must have extensive use by a minimum of three investigators with independently funded projects. Established and junior investigators with expertise outside the NIDCD mission areas who may transition into NIDCD mission areas are encouraged to use P30 services, but do not count toward the requisite three users.

Examples of research cores include: provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); complex instrumentation (e.g., electron microscopy, imaging, engineering); animal preparation and care (e.g. transgenic animal); and service (e.g., molecular biology, DNA sequencing, biostatistics, patient database). The administration of services and prioritization of user requests within each research core must be considered and each research core must have a plan for quality control, when appropriate.

Limited developmental research may also be an appropriate function of a research core if it is directly related to enhancing the functioning, utility or methodology of the core and is not an undertaking that could be supported through other funding mechanisms.

IV. Administration

Organizational Description and Requirements

A Core Center should constitute an identifiable organizational unit within a single grantee institution or a consortium of cooperating institutions. Such a Core Center may involve interaction of broad and diverse elements; thus, lines of authority by the appropriate institutional official must be clearly specified.

The applicant institution will specify a Core Center Director to be responsible for the organization and operation of the Core Center. The Director should be an experienced and respected individual who can provide scientific and administrative leadership for the total program. The Director must be able to coordinate, integrate, and provide guidance in establishment of new research programs. The organization of the Core Center administrative core should include a structure sufficient to coordinate and integrate the Core Center activities, determine the distribution and utilization of funds, and provide advice to the Core Center Director about the activities of the Core Center.

While the final administrative structure of the Core Center will, for the most part, be left to the discretion of the applicant, the effective development of a Core Center requires

close interaction among the Core Center Director, research core directors, the principal investigators of the funded grants utilizing the core, appropriate institutional administrative personnel, and other members of the institution in which the Core Center is located. Therefore, each Core Center applicant should establish and describe an administrative structure that will permit the development of such interaction. This structure will be evaluated as part of the review process (see section VIII.C.).

Institutional Facilities

While facilities available will be described in each research core in the application, a more general description of overall facilities and a statement regarding institutional commitment to the Core Center should be included in the overall description.

Applications from institutions which have a General Clinical Research Center (GCRC) funded by the National Center for Research Resources (NCRR) at NIH may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from the Program Director of the GCRC should be included with application material in the Administrative Core.

V. Human Subjects/Vertebrate Animals And Inclusion Of Women, Minorities And Children In Study Populations

Human Subjects

All research cores involving human subjects at any time during the proposed project period must comply with the regulations for Protection of Human Subjects, 45 CFR 46. See PHS Form 398 for variations allowed by applicant organizations. For each core that involves human subjects and is not exempt from the regulations, address the six points listed in the Instructions for PHS 398.

In many instances, the research cores encompass research supported by research project grants for which the IRB review of human subjects is already complete or an exception is already designated. This review or exemption designation is sufficient, provided the IRB determines that the research is not substantially modified by the Core. The appropriate grants must be identified along with their IRB review dates or exemption designation (in Section 1: Budgets and Other Supporting Forms).

Vertebrate Animals

All activities involving live, vertebrate animals to be supported by NIDCD must be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (revised 9/86). Evidence must be provided that each research core that involves vertebrate animals has been reviewed and approved by the Institutional Animal Care and Use Committee. For each research core that involves vertebrate animals, address the five points listed in the Instructions for PHS 398.

In many instances, the research cores encompass research supported by research project grants for which IACUC review is already complete. This review is sufficient, providing the research is not substantially modified by the core. The appropriate grants must be identified together with their IACUC review date (in Section 1: Budgets and Other Supporting Forms).

Inclusion Of Women And Minorities In Research Involving Human Subjects

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>); a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm:

The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion Of Children As Participants In Research Involving Human Subjects

It is the policy of NIH that children (i.e. individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt data after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address:

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

Investigators may obtain copies from these sources or from their NIDCD Program Officer at the address listed below.

VI. Pre-Application Process

Individuals from institutions with potential interest in applying for a Core Center grant are strongly encouraged to discuss the potential application with the NIDCD staff members identified below. Potential applicants are encouraged to make this contact as early as possible in the application preparation process. The Program Announcement will list a date by which a Letter of Intent is requested. This letter should list the key participants, and provide a description of the currently funded research base as well as the proposed research cores.

The program staff who should be contacted are:

Balance/Vestibular Program:

Daniel A. Sklare, Ph.D.
Scientific Programs Branch
Division of Extramural Research
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Tel: (301) 496-1804
Fax: (301) 402-6251
Email: daniel_sklare@nih.gov

Hearing Program:

Amy M. Donahue, Ph.D.
Division of Extramural Research
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Telephone: (301) 402-3458
Fax: (301) 402-6251
Email: amy_donahue@nih.gov

Smell/Taste Program:

Barry J. Davis, Ph.D.
Scientific Programs Branch
Division of Extramural Research
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180

Phone: 301-402-3464
Fax: 301-402-6251
Email: barry_davis@nih.gov

Speech and Voice Program:

Lana Shekim, Ph.D.
Scientific Programs Branch
Division of Extramural Research
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Phone: 301-496-5061
Fax: 301-402-6251
Email: lane_shekim@nih.gov

Language Program:

Judith A. Cooper, Ph.D.
Scientific Programs Branch
Division of Extramural Research
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Phone: 301-496-5061
Fax: 301-402-6251
Email: judith_cooper@nih.gov

For fiscal and administrative matters, contact:

Ms. Sherry Dabney
Grants Management Branch
Division of Extramural Research
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Telephone: (301) 402-0909
Fax: (301) 402-1758
Email: sherry_dabney@nih.gov

Applications for this program are accepted only in response to a Program Announcement, (PA) published by NIDCD in the NIH Guide for Grants and Contracts, (<http://grants.nih.gov/grants/guide/pa-files/PA-01-011.html>).

VII. Application Format And Content

VII.A. General Information

The Core Center application should be arranged in the format as specified below.

Form PHS 398 (Rev 5/01) must be used for the Core Center application. Individual cores should be prepared and written separately on Form PHS 398. The arrangement of materials should follow both the instructions in Form PHS 398 application kit and the more specific instructions detailed below. Applications not in accordance with Core Center guidelines will be returned to the applicant without further review.

The original and three (3) signed, exact photocopies of the application should be sent to:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 ROCKLEDGE DR MSC 7710
BETHESDA MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

In addition to mailing the application to the Center for Scientific Review, send two (2) copies of the application, plus five (5) sets of any appendices, to:

Chief, Scientific Review Branch
National Institute on Deafness and Other Communication Disorders
6120 Executive Boulevard, EPS 400C
MSC 7180
Bethesda, MD 20892-7180
Rockville, MD 20852 (for express/courier service)
Telephone: (301) 496- 8683

VII.B. Content Order for Applications

Applications should be written in the style and within the page limitation described in the PHS 398 instruction kit and the applications guidelines below. Applicants may also consult with NIDCD staff concerning the technical aspects of preparing the application.

Face Page of Form PHS 398 (Rev 5/01). Complete all items on the face page as directed. In the title block, item 1, put "Core Center." Mark item 2 "yes" and write in Program Announcement Number PA-01-011. Add "NIDCD: Research Core Center P30" for the title.

Page 2: Describe the proposed Research Core Center (P30) indicating the goals and objectives of the research cores. Do not exceed the space allowed. Key personnel are

Core Center Director, Associate or Co-PI Director (optional), research core directors, participating investigators who will use any research core to a moderate or extensive degree, and consultants.

Table of Contents: Discard this page from Form PHS 398 and prepare a Table of Contents appropriate for the Core Center application. The Table of Contents should list 4 sections: *Section 1, Budget and Other Supporting Forms*, should include all budgets, biographical sketches, other support, human and animal assurances table; *Section 2, Biomedical Research Base*, should include the general overview of the P30, and presentation of the research base; *Section 3, Administration*, should include the administrative structure, facilities and equipment, floor plans and/or campus maps, and letters of institutional commitment and support; and *Section 4, Research Cores*, should include a brief overview of the research cores, followed by separate sections using PHS 398 for each research core. Each core should be listed by the title. Specifically list the location of the checklist, which is the last page of the application. If appendices are to be included, these should be listed in *Section 5, Appendices*.

VII.B.1. Budgets and Other Supporting Forms

(The following budget information applies to *Section 1: Budgets and Other Supporting Forms* as well as *Section 4, Research Cores*, since there will be budget information in both.)

Budget: Use Form Pages 4 and 5 in PHS Form 398 for all budgets. Justify and document all costs for current and future years throughout. Details and justifications for all budget items below must be part of the individual budgets. See the Instructions for PHS 398 on how to prepare budget pages and justifications.

The overall Core Center budget, “Summary Center Budget,” is to be presented first using PHS 398 Form Page 4 entitled “Detailed Budget for Initial Budget Period Direct Costs Only” (see sample document 1). Presentation of a consolidated budget for the first 12 months should then follow in a tabular form, providing information on budgetary categories for the administrative and each research cores (see sample document 2). Form Page 5 of PHS 398, “Budget for Entire Proposed Period of Support Direct Costs Only”, should follow next, summarizing all individual budgets and administrative costs (see sample document 3). For the purpose of establishing future year budget requests, the applicant should not exceed cost escalations specified by the NIH.

Separate budget pages and justifications for the overall Core Center administration and for each individual research core, initial year and 5 year composite, should be included later in the application with each research core for which funding is sought and should not be repeated elsewhere in the application. The potential for budgetary overlap between the user research projects and the P30 cores, specifically overlap of personnel effort as well as all other expenditures, must be discussed. In some instances, overlap will be minimal. In others, budgetary overlap could be considerable. Specifically address the strategies for deciding what expenses will be charged to the P30 versus the participating

research grants. A statement should be provided indicating how budgetary expenses for the user R01s, P01s, or any other funding mechanisms with potential overlap, will/will not be modified upon receipt of the P30 award. A strategy for reimbursement of core services should be delineated to ensure no duplication of funding. NIDCD program and grants management staff will negotiate with both the Core Center Director and the Principal Investigator of ongoing research project grants utilizing P30 facilities regarding potential budgetary overlap.

Personnel: The Core Center Director will have responsibility for overall direction of the entire Core Center (P30). Additionally, a director should be named for each research core. A research core director must be an expert with an independently funded research program that will use the core services. The percent effort for a research core director should be relatively low. NIDCD support for salary for each research core director is limited to 10%. In the unusual circumstance that a core director requests greater than 10% effort, it must be justified through activities beyond typical administrative functions. Additional levels of commitment beyond 10%, supported by the university and not requested from the NIDCD, should be noted in the application as institutional commitment.

Limited support for administrative staff may be requested to the extent that it relates directly to the management of Core Center activities. Justification for administrative support should describe fully the duties to be performed. This justification will be closely scrutinized, as efficient administration is expected.

Support for technical personnel or positions to be filled in research cores may be included. The time and salary of all technical and support personnel must be related to their effort on the research core. Technical support personnel may receive up to 100% salary support from the Center. A technician can not be a core director.

Equipment: This grant mechanism is not intended for the acquisition of equipment which should be funded through other sources or through other funding mechanisms (e.g., NCRR Shared Instrumentation Grant). No equipment item over \$3,000 may be requested without prior approval (see below).

Under exceptional circumstances, where expensive items of equipment are needed, the application must document available equipment within the institution and provide clear justification for requested equipment in terms of core service to be provided. In addition, the potential for cost sharing must be explored prior to the application submission and the results of such exploration (i.e., institutional commitment demonstrated through cost sharing) must be clearly stated in the application. The inclusion of expensive items of equipment must be approved with NIDCD program staff listed in Section VI. prior to the submission of the application.

Supplies: Consumable supplies directly related to the operation of the cores (photographic supplies, electronics parts, machine shop stock, tissue culture media, glassware, chemicals, animals, etc.) are allowed.

Travel: Appropriate travel requests include travel of scientific, technical, or administrative staff for training that would enhance the quality of a research core or travel required to maintain the operation of a core. However, this training must take place in a focused, active intensive training session or a specific course or workshop, as opposed to a session at a national meeting or the equivalent.

Consultant Costs: Consultant costs may be requested.

Other Expenses: Equipment maintenance, maintenance contracts, and computer time are examples of the many types of allowable costs.

Consortium/Contractual Costs: Funds may be requested. Subcontracts to foreign organizations are not allowed.

Items not allowed: Funds for alteration and renovation, rental space, direct support of individual research projects, salary and support for central institutional administrative personnel or secretarial support that is usually paid from institutional overhead charges, travel of investigators, or page and publication charges for staff investigators are not allowed. Equipment exceeding \$3,000 must be pre-approved by NIDCD program staff.

Biographical Sketches: Biographical sketches are required for key professional personnel, which includes the Core Center director, and research core directors (including consultants) in the Core Center application. Biographical sketches are also required for the principal investigator of each grant listed in the research base. The forms found in **Form PHS 398 (Rev 5/01)** should be used. Place individual sketches in alphabetical order. These pages should not be duplicated in the individual research cores.

Other Support and Research Base Summary: Other support should be listed for all individuals listed in the Key Personnel section, with the exception of consultants. These pages should not be duplicated in the individual component projects and cores.

Assurance Documentation: A master table listing the status of human subject and the animal usage approval dates should be included.

VII.B. 2. Biomedical Research Base of the Core Center

This section is presented on continuation pages in narrative fashion.

General Overview of the Core Center: The goals and objectives of the Core Center should be explicitly stated. This section should not exceed two single-spaced pages, should state concisely any areas of special interest, and should identify any research

ideas, disease entities, and target populations to be studied. Applicants will include an overview of current research conducted at their institution in sufficient detail to allow reviewers to judge its extent and the interrelationships of ongoing research. Interrelationships among Center members, quality and productivity of the research programs, demonstrated or potential interdisciplinary coordination, and how establishment of a Core Center will further extend, stimulate and provide added dimensions to the current research activities are all important considerations for review and subsequent funding.

Presentation of the research base: Begin with an abstract, no longer than half a page, summarizing the research base. This should be followed by a section, not to exceed 5 pages, addressing the scientific focus and demonstrated or potential collaborations/interrelations of research conducted by Core Center investigators.

Research projects included in the research base should be grouped into aggregates of projects with similar overall goals and objectives since an assessment of the research base is important as a primary criterion in the evaluation of applications. Since most, if not all, of the research base will have undergone separate peer review, the quality of the individual funded projects is already established. The more important aspects will be: (1) interactions and interrelationships of the research efforts; (2) uses and benefits of core services; and (3) plans to continue/develop productive collaboration among Core Center investigators. Documentation of a collaborative environment may be included here (listing of co-authored publications from P30 user PIs).

Size of the research base. To document the research base of the proposed Core Center, a table listing the grants, funding source and duration, the current year budget (direct cost), and their principal investigators is required. Current year total direct cost dollar amounts for research grant in the research base of the Core Center must be provided.

Competing Continuation Applications: Include a general progress report that highlights achievements under the Core Center since the last competitive review. Include the following information:

- (1) A summary of major accomplishments that can be attributed to the Core Center program and a brief explanation of how these accomplishments have contributed to the achievement of the stated objectives of the grant.
- (2) A list of changes, if any, in professional staffing since the last competitive review.
- (3) A list of all publications, including those in press, that have resulted from the Core Center grant. Do not include manuscripts in preparation or under review.

VII.B.3. Administration

Administrative activities of the overall Core Center which are not contained in the separate research cores (e.g., Core Center Director percent effort) should be presented as

a separate administrative core. Presentation of the administrative structure (See Section IV) should follow the presentation of the research base and should include a discussion of the Director and if designated, Associate Director, as well as the relationship and lines of authority and sanction by appropriate institutional officials. Administrative costs for the P30 are intended to be minimal. Thus strong justifications for administrative costs must be provided.

Facilities and General overall description of facilities and institutional commitment including letter(s) of institutional commitment and, if applicable, of the General Clinical Research Center Director. The description of the physical arrangements and instrumentation for the cores should be included. Campus maps and floor plans of space for the cores of the Core Center may be helpful in certain circumstances.

Institutional commitment to provide space or to share in the cost of purchasing equipment needs to be documented. Core Centers are encouraged to enter into cooperative arrangements with established cores in other centers or resource grants offering a similar type of service at the applicant's institution.

VII.B.4. Research Cores

Overview: Introduce this section with a narrative overview of all of the proposed research cores and their impact on ongoing research. The justification will likely vary based on the purpose. The purpose of each research core may vary, such as providing increased efficiency for routine ongoing services, promoting or enhancing new or ongoing collaborations, and/or providing new and innovative resources or services currently unavailable.

Research Cores: (See Section III) Present each core separately using Form PHS 398 (Rev 5/01) with an abstract and research plan that includes all the items in PHS 398. Instructions specific to the P30 follow below. The presentation for each research core (sections 4 – 8 below) is limited to 25 pages. It is not a necessity to use all 25 pages.

(1) Summary page: Use PHS Form 398 Form Page 2.

(2) Budget: Provide comprehensive justifications for the budget and discuss issues of overlap, accounting strategies for future expenses, as well as mechanisms for reimbursing core services if appropriate.

(3) Resources and Environment: Special attention should be given to describing the space and resources available for the core service(s) proposed. The location of the core services performance sites and the physical relationship of the core resources to the core users should be included. This section will likely be longer than in an R01 application.

(4) Specific Aims: Describe the broad, long-term objectives and goals of the core. Delineate the services to be provided.

(5) Background and Significance: State the reasons why a core is needed. This justification should include a. how the core will provide increased or innovative/new capabilities, b. how the core will facilitate increased productivity and effectiveness of ongoing research projects, and/or c. how the core will facilitate collaborative research. These must be justified beyond what is currently available through R01 support. For all user R01s, articulate how the core services will likely benefit the research accomplishments within each R01, and if appropriate, how the core services may enhance collaborative research efforts for that R01. The ability to articulate user benefit is a critical factor in review. Both major and minor users of the core should be included. This section will likely be longer than in an R01 application.

A minimum of three funded-investigator users does not in itself provide sufficient justification. A larger number of NIDCD-funded investigators using each core to a moderate or extensive degree would generally strengthen the justification. In the event that a proposed research core is not in use 100% of the time, the application must justify this circumstance.

A table is helpful to describe for reviewers the projected use (both period of core use and degree of use) of the proposed core by funded investigators.

(6) Prelim Studies/Progress Report. (This section should primarily be used for competing renewals or competitive supplements). For new applications, this section will likely be shorter than in an R01 application and may include examples of previous/ongoing services/techniques that have provided increased productivity within the research environment. Competing continuation applications should document the impact the Core Center has had. Publications, new collaborations, and other outcomes of the core should be documented. Information on core usage and information on core benefit to the scientific research enterprise should be discussed. Specific problems in core administration and management should also be noted.

(7) Research Design and Methods: Each proposed technique or service should be described in enough detail to allow the reviewers to do a comprehensive evaluation. Are personnel and equipment in place to provide the services? Existing methodologies already in use at the institution may be very briefly described. Methodologies new to the institution should be described in greater detail and strategies for successful implementation should be delineated. Include any developmental methods research or training, if proposed. If applicable include sections on quality control. Sections on gender, minority and children inclusion should be included as appropriate, in addition to Human Subjects/Vertebrate Animals (see PHS 398 Instructions). If not applicable, mark them N/A.

(8) Administration and Organization: The administration, organization and proposed management of the core should be included and is a critical issue in review of the application. A plan to implement core services and prioritize investigator use should be

presented. If the core is used to train investigators in special techniques, the nature and extent of this training should be described and the qualifications of core personnel to provide and oversee this training should be described.

(9) Literature Cited and (10) Consortium/Contractual Arrangements: If not applicable, mark them N/A.

VII.B.5. Appendices

Appendices may be submitted with P30 applications to the NIDCD. If such materials are submitted, they should be mailed separately from the application and sent directly to the NIDCD Scientific Review Branch at the address listed in Section VII.A. Include key reprints and other supporting material. See PHS 398 Instructions. Different sections of the Core Center application may be reviewed by different reviewers, thus each piece of appendix material should be labeled with the Center Director and the research core to which it belongs.

All appended material must be packaged and clearly identified with the appropriate research core. No more than ten reprints or manuscripts accepted for publication may be submitted for any research core. Five complete and collated sets of Appendix material must be received by the NIDCD Scientific Review Branch within three weeks of the submission of the P30 application.

VII.B.6. Revised Applications

All revised applications must have an introduction. Do not exceed two pages of introduction for the overall P30 and three pages of introduction per core. All changes in the research plan must be clearly marked.

VII.B.7. Supplemental Applications

A competitive supplemental application requesting the addition of a research core(s) to an existing P30 is allowed, but may not exceed the term of award of the parent P30. These applications are due on the standard NIH receipt dates, and must be in accordance with all previously outlined P30 criteria. NIDCD program staff should be contacted as early as possible to determine eligibility.

VIII. Review Procedure And Criteria

VIII.A. Review Process

Applications for Core Center grants will undergo an initial examination for completeness by the Center for Scientific Review and for responsiveness by NIDCD staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive will be evaluated for

scientific and technical merit in accordance with the standard NIH procedures by an initial review group (IRG) convened by the NIDCD. As part of the initial review, all applications will be discussed and receive a written critique. Those applications deemed to have the highest merit, generally the top half of applications under review, will receive a second level of review by the NDCD Advisory Council.

As part of the initial scientific review, reviewers will rate the Core Center and each individual research core; the scores will appear in the summary statement. Since the NIDCD is interested in funding only the best research, individual cores of lesser quality (for example, those falling below the score of fundable Core Center applications) may not be funded, even if recommended, under the “umbrella” of the Core Center grant application.

Each individual core must fit in and contribute to the overall Core Center and each application should be complete at the time of submission. Site visits are not anticipated.

VIII.B. Review Criteria for Individual Research Core

Individual research cores are evaluated on the facilities/services provided, their utility, and their ability to fulfill the goals of the Core Center program. Important factors include:

- Significance of the core support to the research base. How the core will support and enhance ongoing research projects beyond currently available resources.
- The potential of the core to promote collaborative research and/or attract new investigators to research in communication disorders.
- The potential of the core to provide increased efficiency of services.
- The potential of the core to offer services which are new, unique or otherwise unavailable on individual R01s.
- The administrative management of the core, including implementation, allocation, user prioritization, quality control and utilization of services.
- Training and appropriateness of the core director and personnel, the commitment of the investigators, and the ability to devote the required time and effort to the core.
- Adequacy of the facilities, equipment and institutional commitment to the core.

In addition to these criteria, in accordance with NIH policy, all applications will be reviewed with respect to the following:

- The adequacy of plans to include children, both genders, minorities, and their subgroups, as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.
- The reasonableness of the proposed budget and duration in relation to the proposed research.
- The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

VIII.C. Overall Core Center Evaluation

An overall priority score will be assigned to the application. The score will reflect not only the quality of the individual cores, but also plans for leadership and administration, and how the proposed Core Center will enhance the research base.

The following elements will be evaluated:

Leadership and Administration:

- The plans for coordination of ongoing research between the separately funded projects and the Core Center including mechanisms for internal monitoring.
- The plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators.
- Appropriate scientific and administrative leadership, and the time commitment of the Core Center Director for the effective management of the Core Center program.
- The management proposed for fiscal administration, procurement, property and personnel management, planning, budgeting, etc.
- The overall environment for a Core Center. This includes the institutional commitment to the program, lines of accountability regarding management, and the institution's partnership with the Core Center. This also includes the academic environment and resources in which the activities will be conducted, such as the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.

Research Base and Enhancement by the Core Center

- The relevance and interrelation of these separately funded research projects to the central themes of the Core Center.
- The likelihood for new or enhanced collaborations among Core Center investigators. This includes demonstrated interactions and interrelationships of the research efforts as well as plans to further develop productive interdisciplinary collaborations among Core Center investigators.
- Ability of the Core Center to significantly enhance (further extend, stimulate and provide added dimension to) the established research base of the host institution.

Competitive Renewal Applications

In a competing continuation application, the application should document the impact the Core Center has had. This includes the qualifications, experience, and commitment of the Core Center investigators and their proven ability to interact with each other and attract additional investigators to the mission areas of the NIDCD. In addition to the previously stated criteria, reviewers will consider the following:

- Significance of the contribution of products and services from these individual cores to the research base.
- Evidence that the Core Center shared resources effectively and efficiently. The extent of core utilization by individual principal investigators associated with the research base.
- Effectiveness of the Core Center in facilitating collaborations or helping to attract investigators to communication disorders research.
- Ability of the individual cores, and overall Core Center, to provide a significant advantage beyond what could practically or efficiently be supported on individual research grants.

IX. Reporting Requirements And Annual Evaluation

Annual progress reports, submitted as part of the annual noncompeting continuation application are due two months before the anniversary date of the award. These reports are used by the NIDCD and advisory committees to review the Core Center and its progress. A progress report containing the following information is to be submitted with the annual continuation application (PHS Form 2590). The report should include the following:

A detailed summary of each Core Center research core, including the Core Center Director and key personnel, their percent efforts, budgets, description, progress and evaluation. It is especially important that the significance and utility of each research core be discussed in the summary description;

1. A budget of the estimated use of funds for each research core. In conjunction with the programmatic description, this report will describe allocations in the usual budget categories (e.g., personnel, supplies) as well as the total expenditures. Separate budget pages should be used for research core in addition to a composite budget for the entire Core Center;
2. A table showing all support associated with the Core Center. This should include both federal and non-federal support. At a minimum, this would include all individual research grants, center grants, training grants, National Research Service Awards, career development awards, etc. The table should list, for each source of support, the title of the project, name of the principal investigator, identifying number of the grant, percent effort of the investigator, dates of support, and current annual support (direct costs);


3. A discussion of the effectiveness of the Core Center in furthering the goals of the Core Center programs. This should include a summary of the specific accomplishments that can be attributed to the Core Center grant. List what has been accomplished with the Core Center and what would not have been done without it; e.g., new research findings, new investigators brought to the field, patients seen, or organizational improvements within the institution;
4. A discussion of any problems which impede accomplishment of the stated goals in the administration of the Core Center grant;
5. A summary (equivalent to no more than 2 single-spaced pages) of the goals and significant activities of the Core Center. This summary should be prepared for a general audience (as compared with item 1 above, which should contain much more detail);
6. A list of all collaborative efforts which the Core Center has established and is conducting with other institutions/Core Centers. This list should include a description of each activity, identification of the other Core Center(s) involved, and any results obtained so far;
7. Other information that, from year-to-year, may be requested by NIDCD staff.

The expanded progress report is in addition to, and does not replace, other management reports required by PHS policy. In addition to the annual progress report, NIDCD program staff may conduct site visits to gain added insight into the various aspects of the Core Center operations.

X. Sample Documents

- Sample I. Detailed Budget for Initial Budget Period (Form page 4)
- Sample II. Consolidated Budget for First Year (Table Form)
- Sample III. Budget for Entire Proposed Period of Support (Form page 5)

Principal Investigator/Program Director (*Last, first, middle*): **SAMPLE #1**

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM	THROUGH	
PERSONNEL (<i>Applicant organization only</i>)		TYPE APPT. (<i>months</i>)	EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (<i>omit cents</i>)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						
 SUBTOTALS							190,000
CONSULTANT COSTS							3,000
EQUIPMENT (<i>Itemize</i>)							32,000

SUPPLIES *(Itemize by category)*

22,000

TRAVEL

PATIENT CARE COSTS

INPATIENT

OUTPATIENT

ALTERATIONS AND RENOVATIONS *(Itemize by category)*OTHER EXPENSES *(Itemize by category)*

21,000

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD

\$

CONSORTIUM/CONTRACTUAL DIRECT COSTS

COSTS

FACILITIES AND ADMINISTRATIVE COSTS

—▶ TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)***\$268,000****SBIR/STTR Only: FIXED FEE REQUESTED**

Sample 2: Consolidated Budget for First Year

Budget Category	Admin	Core 1	Core 2	Core 3	Total
Personnel	5,000	60,000	75,000	50,000	190,000
Consultant Costs			3,000		3,000
Equipment		14,000	6,000	12,000	32,000
Supplies		12,000	5,000	5,000	22,000
Travel					-----
Patient Care Costs					-----
Other Expenses		6,000	5,000	10,000	21,000
Consortium/ Contractual Costs					
Total Direct Costs for Initial Budget	5,000	92,000	94,000	77,000	268,000

Principal Investigator/Program Director (Last, first, middle):

SAMPLE #3

h

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY

BUDGET CATEGORY		INITIAL BUDGET PERIOD <i>(from Form Page 4)</i>	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
TOTALS						
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>		190,000	195,700	201,571	207,618	213,846
CONSULTANT COSTS		3,000	1,000	1,000	1,000	1,000
EQUIPMENT		32,000	7,000	7,000	7,000	7,000
SUPPLIES		22,000	22,660	23,340	24,040	24,761
TRAVEL						
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES		21,000	21,630	22,279	22,947	23,635
SUBTOTAL DIRECT COSTS						
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
	F&A					
TOTAL DIRECT COSTS		268,000	247,990	255,190	262,605	270,242

TOTAL DIRECT COSTS FOR ENTIRE
PROPOSED PROJECT PERIOD (Item 8a, Face Page)

1,304,027 \$

SBIR/STTR Only Fixed Fee Requested					
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SBIR/STTR Only: Total Fixed Fee Requested for Entire Proposed Phase II Period	
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(Add Total Fixed Fee amount to "Total direct costs for entire proposed project period" above and Total F&A/indirect costs from Checklist Form Page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.)

\$

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.